

	Type	L #	Hits	Search Text	DBs
1	IS&R	L1	1	("6258116") .PN.	USPAT
2	IS&R	L2	1	("6017363") .PN.	USPAT
3	IS&R	L3	1	("5938682") .PN.	USPAT
4	BRS	L4	230	bifurcat\$ and stent and weld\$	USPAT

	Time Stamp	Comments	Error Definition	Errors
1	2003/01/09 15:33			0
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TITLE: Stent or graft support structure for treating bifurcated vessels having different diameter portions and methods of use and implantation

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Stent or graft support structure for treating bifurcated vessels having different diameter portions and methods of use and implantation

A self-expanding stent structure is provided having a main portion that expands to a first diameter and a branch portion that expands to a second diameter, different the first diameter, the main portion having a link portion that forms a flexible linkage to, and forms part of, the branch portion. The self-expanding structure may be compressed to a reduced diameter for delivery, and resumes an expanded diameter during deployment. The self-expanding stent structure also may be advantageously incorporated in an asymmetric stent-graft system. Methods of use are also provided, wherein the main portion of the self-expanding structure, when deployed in a trunk vessel, may be used to anchor the branch portion in a branch vessel.

The present invention relates generally to minimally invasive techniques for treating occlusive vascular disease, for example, in the carotid, renal, femoral and cerebral arteries, and for repairing aneurysms occurring in bifurcated organs or vessels, such as the abdominal aorta.

In occlusive vascular disease, such as arteriosclerosis, plaque accumulates within a vessel and gradually narrows the vessel to the degree that the vessel can no longer supply an adequate flow of blood. A number of vascular prostheses have been developed to re-expand and retain the patency of such afflicted vessels, for example, after atherectomy or angioplasty. U.S. Pat. No. 4,733,665 to Palmaz describes one type of balloon-expandable stent structure to treat occlusive disease.

It is often desirable to support a tortuous vessel, or one having a diameter that changes along the length of the vessel. U.S. Pat. No. 5,421,955 to Lau et al. describes a stent comprising a series of linked sinusoidal rings. That patent describes that the individual sinusoidal elements may be differentially expanded to accommodate diameter changes in the vessel.

A drawback of the foregoing previously known devices, however, is that such devices are not readily deployable in bifurcated vessels, so that one portion of the stent may be deployed in a trunk vessel having a large diameter, and a second portion of the stent may be deployed in a branch vessel having a much smaller diameter. Moreover, because branch vessels often form an angle with trunk vessels, previously known devices cannot be readily employed in such environments.

With respect to treatment of aneurysms, previously known minimally techniques generally seek to "re-line" a flow path through the organ, for example, by fixing a graft across the weakened tissue of the aneurysm. The graft is then held in place with one or more stents, which may be implanted, for example, using a balloon catheter. Such arrangements are described, for example, in

Parodi U.S. Pat. No. 5,219,355, European Application No. 0 461 791, and
Clouse U.S. Pat. No. 5,211,658.

A number of techniques also have been developed for deploying graft systems in bifurcated anatomy, such as the aorto-iliac bifurcation.
For example, U.S.

Pat. No. 4,562,596 to Kornberg describes a graft comprising a main portion having first and second legs extending therefrom. The main portion is deployed in the aorta, while the first and second legs are deployed in the iliac arteries. U.S. Pat. No. 5,360,443 to Barone et al. and U.S. Pat. No. 5,489,295 to Piplani et al. describe similar devices.

Other bifurcated graft systems, as described in U.S. Pat. No. 5,575,817 to Martin and U.S. Pat. No. 5,609,627 to Goicoechea et al., so called "asymmetric grafts," comprise a main portion having a long first leg, and a much shorter second leg. The grafts are deployed so that the long leg is disposed in the iliac artery used to gain access to the aorta, and so that the short leg does not extend into the contralateral iliac artery. In a separate step, an extension portion is then attached to the short leg, thus extending the second leg into the contralateral artery.

In view of the foregoing, it would be desirable to provide a stent having first and second portions that may be deployed to different expanded diameters.

It would further be desirable to provide a stent capable of being deployed in a bifurcated vessel that enables a first portion of the stent to be deployed in a trunk vessel having a first longitudinal axis, and a second portion of the stent to be deployed in a branch vessel having a second longitudinal axis, the second longitudinal axis forming an angle with the first

longitudinal axis.

It would be still further desirable to provide a stent structure suitable for use as a support element of a bifurcated graft system.

It would be yet further desirable to provide methods of constructing and deploying a stent-graft system that overcome drawbacks of previously known stent and stent-graft systems.

In view of the foregoing, it is an object of the present invention to provide a stent having first and second portions that deploy to different expanded diameters.

It is another object of this invention to provide a stent capable of being deployed in a bifurcated vessel, wherein a first portion of the stent is deployed in a trunk vessel having a first longitudinal axis, and a second portion of the stent is deployed in a branch vessel having a second longitudinal axis, the second longitudinal axis forming an angle with the first longitudinal axis.

It is a further object of the present invention to provide a stent structure suitable for use as a support element of a bifurcated graft system.

It is a still further object of the present invention to provide methods of constructing and deploying a stent-graft system that overcome drawbacks of previously known stent and stent-graft systems.

These and other objects of the invention are accomplished by providing a self-expanding stent structure comprising a first portion having a first expanded diameter and a second portion having a second expanded diameter. The

self-expanding stent structure comprises a main portion configured to be disposed in a trunk vessel having a first diameter and a branch portion configured to be disposed in a branch vessel having a second diameter different than the first diameter. A continuous flexible link extends from the main portion and forms part of the second portion. The self-expanding structure may be compressed to, and constrained at, a reduced diameter for delivery, and resumes an expanded shape during deployment.

In accordance with the principles of the present invention, the stent structure also may be used to support a graft to treat aneurysms occurring in bifurcated organs or vessels, such as the abdominal aorta. Methods of deploying a stent and stent-graft system constructed in accordance with the present invention are also provided.

FIGS. 1A and 1B are, respectively, perspective front and side views of a self-expanding stent constructed in accordance with the principles of the present invention in the deployed state;

FIGS. 2A and 2B are, respectively, enlarged partial views, within view area 2 of FIG. 1A, of the self-expanding stent structure of FIGS. 1A and 1B in the deployed and delivery states;

FIGS. 3A and 3B are, respectively, end views of the self-expanding stent structure of FIGS. 1A and 1B in the deployed and delivery states;

FIGS. 4A and 4B are views depicting deployment of stents constructed in accordance with the present invention at the junctions of the carotid artery and aorta and subclavian artery and aorta;

FIG. 5 is a view depicting deployment of stents constructed in accordance with the present invention at the junction of the carotid and cerebral artery and within the cerebral artery;

FIG. 6 is a perspective view of an asymmetric stent-graft system incorporating the stent structure of FIG. 1; and

FIGS. 7A-7C are views depicting deployment of the stent-graft system of FIG. 6 in accordance with the methods of the present invention.

Referring to FIGS. 1A and 1B, stent 10 constructed in accordance with the principles of the present invention is described. Stent 10 comprises self-expanding structure having main portion 20 coupled to branch portion 22 via flexible link 24. Each of main portion 20 and branch portion 22 are formed from a plurality of longitudinal wire segments 26 welded together at points of contact 28. Wire segments 26 preferably comprise a resilient material, such as a nickel-titanium alloy or stainless steel, and permit self-expanding structure 10 to be compressed to a reduced diameter, as described hereinafter.

With respect to FIGS. 2A and 2B, each wire segment 26 comprises spaced-apart longitudinal segments 30 and 32 interconnected by connecting elements 34. As shown in FIG. 2A, connecting elements 34 are non-orthogonal to longitudinal segments 30 and 32 when self-expanding stent structure 10 assumes its fully expanded, deployed state (as in FIGS. 1A and 1B). When a radially compressive load is applied to self-expanding structure 10, however, the angle α formed between the connecting elements 34 and longitudinal segments 30 and 32 becomes more acute, thus reducing the circumferential distance between longitudinal segments 30 and 32, as depicted in FIG. 2B.

Contraction of self-expanding stent structure 10 also causes apices 36 formed by the wire segments to move towards one another and foreshortens the length of stent 10.

In accordance with the principles of the present invention, stent 10 may be compressed to reduced delivery diameter D.sub.c, depicted in FIG. 3B, wherein the diameters of main portion 20 and branch portion 22 are approximately equal. Stent 10 is then constrained at that reduced diameter for transluminal delivery using a delivery sheath. Once the stent is disposed at a desired position in a vessel, the delivery sheath is retracted, releasing the constraint.

Upon release of the constraint imposed by the delivery sheath, the main and branch portions of self-expanding stent 10 resume expanded, deployed diameters D.sub.E1 and D.sub.E2, as depicted in FIG. 3A. Alternatively, the self-expanding stent structure may comprise a martensitic nickel-titanium alloy that expands to its deployed state by transitioning to the austenite phase upon being exposed to body temperature, as described in U.S. Pat. No. 4,503,569 to Dotter.

Referring to FIGS. 4A and 4B, a method of using stent 10 to treat stenosis S in a patient's internal carotid artery ICA is described. In FIG. 4A, stent 10 is shown disposed within delivery sheath 40 at its reduced delivery diameter D.sub.C. Stent 10 is loaded in delivery sheath 40 so that branch portion 22 is located nearer to distal end 42 of the delivery sheath.

Delivery sheath 40 has distal end 42 positioned within internal carotid artery ICA so that branch portion 22 is aligned with stenosis S. This may be

accomplished, for example, by passing delivery sheath 40 in a retrograde fashion through a femoral artery, descending aorta A, and into common carotid artery CCA in aorta arch AA under fluoroscopic guidance. Push tube 44 is disposed within delivery sheath 40 so that its distal end abuts against the proximal end of stent 10.

Once sheath 40 is positioned as shown in FIG. 4A, push tube 44 is held stationary while delivery sheath 40 is retracted in the proximal direction. As delivery sheath 40 is retracted proximally, first branch portion 22 expands to its expanded diameter D.sub.E1, and then main portion 20 expands to its expanded diameter D.sub.E2. As shown in FIG. 4B, flexible link 24 permits the main portion to be deployed in the common carotid artery CCA, which has a longitudinal axis disposed at an angle to the longitudinal axis of the internal carotid artery ICA. FIG. 4B also depicts second stent 15, constructed in accordance with the present invention, deployed with branch portion 15a disposed in subclavian artery SCA and main portion 15b anchored in the descending aorta A.

As will be apparent from FIGS. 4A and 4B, a stent constructed in accordance with the present invention, such as stents 10 and 15, enable a first portion of the stent to be deployed in a trunk vessel at a first expanded diameter, and a second portion of the stent to be disposed in a branch vessel at a second expanded diameter, and wherein the axes of the first and second portions are not collinear. Consequently, the stent of the present invention may be employed in situations where only a short length of healthy tissue in the branch vessel is available, by using the main portion, deployed in a trunk

vessel, to anchor the branch portion in place. The stent of the present invention therefore may be advantageously employed to treat occlusive disease in a number of other branched vessels, such as the femoral arteries and renal arteries.

With respect to FIG. 5, use of stents 16 and 17 of the present invention in the carotid and cerebral arteries is described. Stents 16 and 17 are miniature versions of the stent of FIGS. 1A and 1B. In FIG. 5, stent 16 is disposed with branch portion 16a disposed in middle cerebral artery MCA just distal of the left anterior cerebral artery ACA, while main portion 16b is disposed in left internal carotid artery LICA. Stent 17 is shown disposed with branch portion 17a disposed in a first branch of the middle cerebral artery B.sub.1 just distal of bifurcation of the middle cerebral artery BMCA, while main portion 17b is disposed in trunk of the middle cerebral artery MCA.

Referring now to FIG. 6, stent-graft system 50 constructed in accordance with the present invention is described. Biocompatible graft material 52 is affixed to, and supported by, self-expanding stent structure 10 of FIGS. 1A and 1B (the details of structure 10 are omitted from FIG. 6 for clarity). Graft material 52 may be affixed to either the interior or exterior of structure 10, using, for example, biocompatible sutures. Stent-graft system 50 includes main portion 54 covering main portion 20, branch portion 56 covering branch portion 22, and cuff 58 for accepting covered stent 60.

Covered stent 60 may be constructed, for example, as described in allowed U.S. patent application Ser. No. 08/820,213 to Khosravi et al., which is incorporated herein by reference, and may comprise a coiled

sheet stent, such as described in U.S. Pat. No. 5,443,500 to Sigwart, having graft material affixed to its outer surface.

Referring to FIGS. 7A to 7C, deployment of graft 50 in abdominal aorta A to reline aorto-iliac bifurcation AIB having aneurysm AN in accordance with the methods of the present invention is described. In FIG. 7A, graft 50 is shown constrained to its reduced delivery diameter D.sub.c and contained within delivery sheath 65. Delivery sheath 65 is inserted along pre-placed guide wire 70 via a surgical cut-down in a femoral artery. Delivery sheath 65 is then advanced through iliac artery I.sub.1 and into abdominal aorta A, so that graft 50 is disposed with main portion 54 in the aorta and branch portion 56 in iliac artery I.sub.1. Proper orientation of graft 50 within aorta A may be determined, for example, using radio-opaque bands disposed on the graft or delivery sheath that are visible under a fluoroscope.

A previously known delivery system containing a covered stent, such as described in allowed U.S. patent application Ser. No. 08/820,213 is then advanced along guide wire 75, and covered stent 60 is deployed with one end in cuff 58 and the other end extending into iliac artery I.sub.2, completing assembly of the stent graft system. Guide wire 75 is then retracted from the patient.

5. The structure of claim 1 wherein the structure comprises a plurality of longitudinal wire segments welded together.

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TITLE: Endoluminal prostheses having position indicating markers

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The present invention relates generally to tubular prostheses, such as grafts, stents, stent-grafts, and the like. More particularly, the present invention provides endoluminal prostheses having discrete position indicating elements which facilitate orienting and deploying the prostheses within body lumens, particularly within branching blood vessels for the treatment of abdominal and other aneurysms.

Proper radial orientation of endoluminal prostheses is also important, particularly when deploying branching and asymmetric prostheses within the tortuous vascular system. If the branches of branching prostheses are not oriented toward their respective branching body lumens, the surrounding body lumen may be distended to adapt to the misaligned prosthesis, or the prosthetic lumen may be distorted or even closed entirely. For example, if the trunk of a bifurcated prosthesis is deployed with a branch oriented 90.degree. from the iliac arteries (i.e., angling dorsally rather than laterally), the prosthetic branch lumen may fold or kink, and will have to at least bend at a sharp angle to enter the laterally oriented iliac. In fact, as branching prostheses are often assembled in situ, it may not be possible to introduce the branch prosthesis into such a misaligned branch port. As

recapture or repositioning of expanded endoluminal prostheses is often problematic, it may even be necessary to resort to an emergency invasive procedure to remedy such misalignment.

Tubular endovascular prostheses are often formed as stent-grafts having a flexible tubular liner or "graft" which is supported by a perforate tubular frame or "stent". The frame perforations define radially expandable structures, while the frame often include metals which are, to some extent, visible under fluoroscopy.

Alternatively, it has been suggested to affix radiopaque lines or image markers to bifurcated grafts in the form of fine wire or chain, either woven into the cloth or applied after weaving, or as an inert paint or plastic. However, the liners of endoluminal prostheses must remain highly flexible, typically being folded when the prosthesis is compressed and unfolding during deployment. Wires, chains, or paints which are sufficiently flexible will generally provide only limited-contrast images when the graft is supported by the obscuring frame, and may become detached from the prosthesis once deployed in the body lumen, with potentially catastrophic consequences. Moreover, imaging of such thin, flexible, low-contrast markers is particularly difficult when the prosthesis is in the high density, radially compressed configuration and disposed within a catheter, as is generally required for intravascular maneuvering.

Co-pending U.S. patent application Ser. No. 08/538,706, filed Oct. 3, 1995, the full disclosure of which is hereby incorporated by reference, describes modular prostheses and prosthetic construction methods.

Provisional

Application Serial No. 60/008,254, filed Dec. 1, 1995, also incorporated herein by reference, describes bifurcated modular prosthetic structures and in situ methods for their assembly.

Published PCT patent application WO 95/21,592 describes a bifurcated endoluminal prosthesis including a bifurcated stent and a second stent. One or more X-ray opaque coils or tubes may be disposed over an arm of the stent structure so that the stents can be aligned and engaged in situ under X-ray monitoring. U.S. Pat. No. 5,387,235 describes a bifurcated graft having radiopaque lines and markers formed of fine wire or chains of inert metal, or of an inert paint or plastic.

In yet another aspect, the present invention provides an endoluminal stent-graft comprising a tubular liner having a lumen which defines an axis and a perforate tubular frame supporting the liner. The frame has a plurality of integral marker elements formed by local variations in the perforations, the integral marker elements defining a pattern which indicates a position of the prosthesis when the prosthesis is imaged within the body lumen. Generally, the frame comprises a radiopaque material, and the marker elements comprise portions that are wider than the adjacent expandable frame arms to provide an enhanced radiographic contrast.

FIG. 1 is a side view of an exemplary cylindrical vascular stent-graft having axially constant characteristics.

FIGS. 5A-C illustrate orientation indicating stent-grafts having a liner that supports marker elements, the marker elements comprising imangible bodies which

define a pattern that facilitates orienting and assembling the prostheses in situ when the prosthesis is imaged fluoroscopically within a body lumen.

FIG. 6 illustrates an endoluminal stent-graft having an alternative orientation indicating marker element structure formed integrally with the frame, according to the principles of the present invention.

FIG. 7 illustrates a method for applying a radiopaque marker element to a polyester liner of an endoluminal stent-graft by painting the liner with a radiopaque compound and covering the marker with an overcoat.

FIGS. 13A and B illustrate a method for deploying a bifurcating prosthesis which includes verifying the orientation of a branch port with port orientation indicating markers while the branch port remains compressed within the delivery catheter, and by advancing a secondary prosthesis through a gate at the expanded port, the gate defined by marker elements on either side of the port centerline.

The present invention provides radially expansible tubular prostheses, particularly grafts, stents, and stent-grafts, which generally include discrete, liner supported marker elements that provide a high-contrast image when viewed under fluoroscopy, ultrasound, or some other surgical imaging modality, so as to facilitate the proper positioning of the prosthesis within a body lumen. The prostheses of the present invention are suitable for a wide variety of therapeutic uses, including stenting of the ureter, urethra, trachea, branchi, esophagus, biliary tract, and the like. The present devices and methods will also be useful for the creating of temporary or long term

lumens, such as the formation of fistulas.

The prosthetic structures described hereinbelow will find use in axially uniform cylindrical prostheses, in preassembled bifurcated prostheses, and as prosthetic modules which are suitable for selective assembly either prior to deployment, or in situ. Such selective assembly of prosthetic modules to form a customized endoluminal prosthesis is more fully described in co-pending U.S. patent application Ser. Nos. 60/008,254 and 08/538,706 the full disclosures of which have previously been incorporated herein by reference.

To secure ring frames 14 in place, and to secure the liner to the perforate tubular frame 12, the liner is typically sutured to the frame. A wide variety of alternative liner/frame attachment mechanisms are available, including adhesive bonding, heat welding, ultrasonic welding, and the like. Where inner and outer liners are used, the ring frames may be sandwiched between the liners and held in place by attaching the liners to each other.

Although the structures and methods of the present invention will at times be described with reference to simple tubular prostheses having a single lumen, it should be understood that the present invention also generally encompasses more complex branching and modular endoluminal prostheses. Referring to FIG. 3, for example, a branching endoluminal stent-graft 60 is assembled from prosthetic modules selected to match the needs of the diseased vascular system of the patient. A common lumen cuffed prosthetic module 62 seals and anchors the assembled prosthesis in the body lumen, typically within the abdominal aorta below the renal arteries and above the left and right iliac arteries. Y-connector module 64 engages cuffed common lumen module

62, and separates the blood flow for the iliac arteries. First angled branching prosthetic module 66 and second angled branching prosthetic module 68 engage the branch lumens of Y-connector module 64 to direct the luminal flow along first and second branching body lumens.

Frame rings 72 of expansible prosthesis 70 may comprise a material which is resilient, malleable, or some combination of the two. When resilient, frame rings 72 will preferably be radially restrained by expansible liner 74, even after expansion of the liner to the predetermined limit. Such a liner-restrained stent-graft structure avoids any loosening of the liner after balloon 78 has been removed. As explained in co-pending U.S. patent application Ser. No. 08/595,944, filed Feb. 6, 1996, the full disclosure of which is also incorporated herein by reference, the cuff 76 of expansible prosthesis 70 often expands only to a predetermined limit, at which an element of either the liner 74 or the frame rings 72, or in some embodiments, the interface between the two, impedes further expansion.

Referring now to FIG. 5A, an orientation indicating bifurcated prosthesis 80 includes a plurality of discrete marker elements 82 which form an orientation indicating pattern 84 when imaged using fluoroscopy, ultrasound, or other imaging modalities. Such bifurcated prostheses will be particularly useful for reinforcing abdominal aortic aneurysms which extend into one or both iliac arteries, and will typically be used in combination with a secondary prosthetic module engaging port 85 to seal the port to the body lumen system. Toward that end, pattern 86 preferably indicates the axial location of the ends, and the axial and radial orientation of port 85, when the

prosthesis is in a radially compressed configuration within a delivery catheter, and after deployment to assist deploying the secondary prosthesis within port 85.

A still further feature of pattern 84 is the two axially separated gates 96 adjacent port 85. The axial positions and separation of these gates gives a visual indicator of the allowable prosthetic module overlap when the prosthesis is deployed and imaged in situ. Modular prostheses having less than a predetermined overlap may not be adequately fixed together, while branches which extend too far into the bifurcated prosthesis may lead to imbalanced flow between the branches, or may even fold over and substantially block the luminal flow to one or both branches.

Generally, an overlap is acceptable when an end (or an associated overlap marker) of a secondary prosthesis is disposed between the gates. Advantageously, the gates are defined by markers on either side of the port centerline, greatly improving the visibility of the markers when the delivery catheter of a secondary prosthesis enters the port. Furthermore, a pattern including such gates provides a clear demarkation of the target path between the markers when advancing a guidewire and/or a delivery catheter into the port 85 of bifurcated prosthesis 80.

Referring now to FIGS. 5B and C, branch secondary prosthetic module 100 and trunk secondary prosthetic module 102 also include image markers 82 which define patterns to facilitate axially positioning and radially orienting these modules within a body lumen, particularly with reference to bifurcated prosthesis 80 described above.

Each of branch module 100 and trunk module 102 include

marker elements 106 which produce an image which is aligned along a prosthetic centerline 104 when the prosthesis is properly positioned relative to the imaging apparatus. Advantageously, such a marker element may be aligned with a guidewire passing through the prosthetic lumen even if no other rotational alignment marker is provided, thereby minimizing the total number of markers. Asymmetric marker elements 108 are radially offset from the centerline markers, preferably defining a radial angle between about 15.degree. and 70.degree. with centerline markers 106, to ensure that the modules are not 180.degree. out of rotational alignment, which could be problematic if the modules have a preferred bend angle or some other asymmetric structure. A roughly 30.degree. radial angle is preferred, as flat thin marker elements will produce smaller images when viewed edge-on that tend to blend into the frame as the angle approaches 90.degree., while smaller angles will be difficult to differentiate. Furthermore, such significantly off-centerline markers are less likely to be overshadowed by subsequent guidewire or delivery catheter placements. Left and right off-centerline markers may be included to ensure the prosthesis is not roughly 180.degree. out of rotational alignment. The asymmetric marker elements can also easily be aligned with the port indicator markers 92 or otherwise consistently aligned with some other imagable structure of the bifurcated prosthesis of FIG. 5A.

A method of deploying branching prosthesis 80 and branch module 100 for treatment of an abdominal aortic aneurysm AAA is illustrated in FIGS. 13A and B. Aneurysm AAA extends along the aortic artery A from below the renal arteries R and onto the iliacs I. The imaging system is typically

oriented toward the plane of the aorta/iliac bifurcation. The catheter is introduced and axially positioned under fluoroscopy so that the prosthesis extends along the weakened aorta and into one of the iliacs. By rotating the catheter until the port indicator marker elements 92 are generally on the side of the opposite iliac, the port can be generally oriented to accept branch module 100. Further alignment can be provided by aligning axially offset opposed markers 94.

8. A prosthesis as claimed in claim 4, wherein the prosthesis comprises a bifurcated tubular body having a trunk portion, a first branch portion, and a branch port for receiving a second branch portion, and wherein the pattern includes at least one marker element adjacent the distal end of the prosthesis which indicates the orientation of the branch port before deployment of the branch port.

16. An endoluminal stent-graft comprising:

17. A stent-graft as claimed in claim 16, wherein the frame comprises a radiopaque material, and wherein the marker elements comprise portions that are wider than adjacent expandable structural elements of the frame to provide an enhanced radiographic contrast.